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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/457,765	12/10/1999	HAROLD M. MOODY	PM265189	8046
909	7590	07/28/2004	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			MELLER, MICHAEL V	
			ART UNIT	PAPER NUMBER
			1654	
DATE MAILED: 07/28/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/457,765

Applicant(s)

MOODY ET AL.

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6, 7 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7, 14-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 1-4, 6, 7, 14-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 14-16 are not supported by the instant specification since there is no support for "charging a portion of the total amount of 6-APA to the reaction mixture at the beginning of the reaction such portion providing a concentration of dissolved 6-APA less than 300 mM and introducing the remainder of the total amount during the remainder of the acylation reaction". Since such support for this phrase cannot be found, this claim must be cancelled and thus claims 15-17 must also. What constitutes a portion ? How much is that ?

Claim 17 introduces "a part of said quantity of the 6-APA", what is that ? There is no enablement for "a part". How much is "a part", 20 %, 50 %, etc. ?

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When is the ampicillin to be formed by the acylation reaction done ? There is no enablement for this in the specification. When would one know when this was achieved ?

Claims 1-4, 6, 7, 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, it is not clear where, "maintaining the total concentration in the reaction mixture" has antecedent basis. There is also no antecedent basis for "the acylation reaction" in the claims.

It is also unclear how one can measure the "total concentration" of 6-APA and ampicillin in the reaction mixture when the whole purpose is to produce the ampicillin. One starts with starting materials and ends up with products. It appears applicant is defining the reaction conditions by defining them in terms of the amount of starting material and ending material (product) which is confusing. Nowhere in the specification can such a description of this be found.

In step iii), the same problem of antecedent basis of the "total quantity of phenylglycine derivative" as stated above. Further, it is confusing at what point in the reaction does the acylation occur and step ii). Applicant needs to present claim 1 with definite steps in chronological order. The metering step is a definite

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step not a "maintainance" step. Metering is a physical step whereas the total concentration being some amount is not.

In claims 2 and 4, it would be clearer if applicant stated that they occurred in step i) and step ii), respectfully.

Claims 14-16 are confusing since it is not clear what a "portion" is. The term, "charged" is also confusing. What exactly is applicant trying to claim ? Further, how much is a portion ? 75 % of the total ? 2% of the total ? This claim is very confusing to the point of being meaningless.

Claim 17 introduces "a part of said quantity of the 6-APA", what is that ? How much is "a part", 20 %, 50 %, etc. ?

When is the ampicillin to be formed by the acylation reaction done ? When would one know when this was achieved ?

### ***Claim Rejections - 35 USC § 103***

Claims 1-4, 6, 7, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 92/01061 taken with WO 95/03420.

Applicant argues that the references do not show the metering step. The references are clear in that the same amount of starting materials and ending materials are used and yielded as in the claimed process. To add slowly and in a meticulous manner as in metering is well known in the art and is fully

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contemplated by the references. One of ordinary skill in the art reading the references would have fully realized that adding in the ingredients slowly in a meticulous fashion would work well. It is simply the choice of the artisan in an effort to optimize the results to add the ingredients in such a fashion. In fact, one would be motivated to do so since adding the ingredients in slowly gives them ample time to react properly with one another and produce a better yield of product.

Applicant argues that one of ordinary would not be motivated to add the reactants by metering them in partially. This is simply not well taken by the examiner. The references clearly wanted to yield the best results possible. To add the reactant in a step wise fashion makes perfect sense since one would want ample time for the reactants to react with one another.

Applicant also argues that they have yielded unexpected results. It is not clear where these results have come from nor that they are based in fact. Applicants must present the results in a declaration by the inventors with a clear explanation of the relevance of each part of the side-by-side comparisons and where such support can be found in the instant specification.

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**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'M. V. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller  
Primary Examiner  
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MVM